Donald G. Norris (SBN 90000)
Douglas F. Galanter (SBN 93740)
Norris & Galanter LLP
523 W. Sixth St., Suite 716
Los Angeles, CA 90014
Tel: 213-232-0855
Fax: 213-286-9499
dnorris@norgallaw.com
dgalanter@norgallaw.com

William F. Cavanaugh (SBN 133461)
William F. Schmedlin (admitted *pro hac vice*)
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Telephone: (212) 336-2000
Fax: (212) 336-2222
wcavanaugh@pbwt.com
wschmedlin@pbwt.com

Attorneys for Defendants
MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' ANSWERING CLAIM CONSTRUCTION BRIEF

Defendants Medicis Aesthetics, Inc., Medicis Pharmaceutical Corp., Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals International, Inc. (collectively, "Valeant") respectfully submit this Answering Brief in further support of their constructions of the disputed terms of the patents-in-suit: Allergan's U.S. Patent Nos. 8,450,475 (the "'475 Patent") and 8,357,795 (the "'795 Patent").

Citations to the sequentially-numbered declaration exhibits are made with reference to Exhibits 1-10 of the Declaration of William F. Cavanaugh attached to Defendants' Opening Claim Construction Brief and Exhibits 11-15 of the Declaration of William F. Cavanaugh in Further Support of Defendants' Claim Constructions.

I. INTRODUCTION

Allergan's opening brief contends that the inclusion of lidocaine into crosslinked hyaluronic acid ("HA") fillers was "against the conventional wisdom" and the inventor on both the '475 and '795 Patents defied the prior art when he "invented" stable, lidocaine-containing HA fillers. Allergan's Opening Claim Construction Brief ("Pl.'s Br.") at 4-5. Neither the patents nor Allergan's opening brief provides any citation to a prior art publication expressing concern over the stability of such a combination.

Allergan cites to nothing because those statements are simply untrue. The prior art teaches that lidocaine can be combined with HA fillers. *See* Exhibit 11, Excerpt concerning Lidocaine Prior Art from Valeant's Invalidity Contentions. One patent application specifically disclosed an HA composition that "may further comprise an anesthetic such as lidocaine." Exhibit 12, U.S. Patent No. 2006/0040894 (filed Aug. 15, 2005) at [0183]. Another patent application actually notes the benefit of combining the two: the HA "composition is stabilizied, by the inclusion of a local anesthetic, e.g., lidocaine." Exhibit 13, U.S. Patent App. No. 2005/0136122 (filed Dec. 22, 2003) at[0068]. The reference goes on to note that "[l]idocaine can have a synergistic effect" on a crosslinked HA composition. *Id.*, at Example 21 [0107]. As far back as 1998, there are patents referencing an injectable composition of crosslinked HA that contains lidocaine. Exhibit 14, U.S. Patent No. 5,731,298 (filed Dec. 24, 1992) at Example 1.

Turning to claim construction, in an effort to formulate an infringement theory, Allergan's opening brief fails to acknowledge those instances in which the patentee acted as his own lexicographer or disavowed portions of the claims in order to preserve their validity. As a result, Allergan ignores the definitions set forth by the inventor in his patents and in the prosecution of those patents. Instead, Allergen opts for generic dictionary definitions that do not comport with what was claimed in the patents and what the U.S. Patent and Trademark Office understood the inventor to be claiming in the patents.

Valeant's constructions are consistent with all of the intrinsic evidence, the extrinsic evidence and the state of the art at the time.

II. CLAIM CONSTRUCTION

A. "Stable"

Violating black letter law that a patent applicant can be his own lexicographer, Allergan ignores the explicit and clear instruction from the inventor as to the meaning of "stable" that he provided in the patents. Regardless of whether "stable" could in the abstract have other meanings, the inventor's explicit definition must be given effect.

Allergan attempts to hide behind the statement that typically "claim terms must be given their plain and ordinary meaning to one of skill in the art." Pl.'s Br. at 7 (quoting *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012)). But this is not true when the patentee has provided his own definition. A patentee may always act as his or her own lexicographer by defining a claim term in the patent. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). A claim term should not be given its ordinary meaning where the patentee has made the choice to refuse that ordinary meaning and provide a definition of his own.

The section Valeant quotes is not a mere "passage[ ] of the specification." Pl.'s Br. at 10. It is first found in the section of the specification entitled "DEFINITIONS" in which the specification specifically acknowledges that the inventor is acting as his lexicographer where the given definition "departs from the commonly used meaning of the term." 4:34-40. The inventor

even lists these characteristics as the properties tested to verify the stability of the devices. 13:30 – 14:23.

The absence of dialogue with the Patent Examiner regarding the claim term "stable" does not support Allergan's construction. In fact, it simply suggests that the Patent Examiner understood the term to be exactly as the inventor defined it. To be "stable" requires the maintenance of a minimum of "one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration."

Allergan object to the inclusion of both "sterile composition" and the 25ºC storage temperature and two-month storage time period. Valeant has agreed to drop those terms from its proposed construction because, while they may be relevant to whether a compound is stable, they are not included in the explicit definition provided by the patent.

Given the inventor's clear decision to act as his own lexicographer, Valeant's construction should be adopted.

B. "Crosslinked HA"[1]

"Covalently Modified" vs. "Chemical Linking"

Allergan concedes that the "chemical link[s]" created during the crosslinking process are covalent bonds. *See* Pl.'s Br. at 15 (stating that "covalently modified" HA would be linked to the crosslinking agent). The prior art supports this. *See* Exhibit 3, U.S. Patent No. 7,902,171 (filed Jan. 12, 2005) ("*Reinmuller II*") at 2:9-16 (characterizing "crosslinkage" as "covalent"); Exhibit 2, U.S. Patent No. 6,521,223 (filed Feb. 14, 2000) ("*Calias*") at 2:26-30 (describing the "cross-linking reaction" as the formation of "covalent bonds").

[1] For purposes of this section, Defendants refer to the '475 Patent's claim terms "HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE)," "hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE)," and "(BDDE)-crosslinked hyaluronic acid," as well as the '795 Patent's claim term "hyaluronic acid (HA) component crosslinked with a crosslinking agent." As noted in the earlier briefing, the only difference between these constructions is the requirement that BDDE serve as the crosslinking agent in the '475 Patent.

Allergan nonetheless seek to create ambiguity where there need not be any. It claims that Valeant's construction would include "HA polymers that have reacted with only one end of a crosslinking agent," which would mean "there would be no 'intramolecular junctions joining the individual polymer molecules . . . into a permanent structure." Pl.'s Br. at 15. But this argument ignores the remainder of the Valeant's construction of this claim term. Valeant's proposal specifies that the HA must have been "covalently modified . . . **to form a macromolecular structure that is water-insoluble** . . . . " This explicitly requires that the covalently-bonded HA connect with other HA, otherwise no water-insoluble, macromolecular structure would be created. Thus, Valeant's construction avoids the problem Allergan suggests.

Water-insoluble

As expected, Allergan does not (because it cannot) dispute that crosslinked HA is water insoluble. Nor does Allergan posit a credible reason to omit "water-insoluble" from the construction of "crosslinked HA." Unlike the situations referenced by Allergan – where parties attempt to add functional limitations or constraints without justification – the water insolubility of crosslinked HA is central to understanding its use in injectable dermal fillers and why there is a distinction between water soluble and water insoluble components to the composition.

There is no question that the water insolubility of crosslinked HA is an important distinguishing characteristic. The '475 Patent referenced a patent that referred to crosslinked HA as water-insoluble. Exhibit 4, U.S. Patent No. 8,124,120 B2 (filed Dec. 22, 2003). The same water insoluble "particles" referenced in that patent are described in the '475 Patent. 7:4-9 (describing the "substantially solid" crosslinked HA "particles" in the less-crosslinked HA "fluidic phase"); *see also Calias* at 4:45 – 5:3 (referring to the crosslinked HA as a "water insoluble biocompatible composition"); Exhibit 5, WO 96/33751 (filed Apr. 25, 1996) ("*Debacker*") at 3:14-19 (describing the highly crosslinked HA as "insoluble fragments of a hydrogel"); Exhibit 6, U.S. Patent App. 2006/0194758 (filed Apr. 8, 2004) ("*Lebreton*"), at [0012] (referring similarly to crosslinked HA as "insoluble fragments of a highly crosslinked polymer hydrogel").

Allergan never squarely addresses the problem that their construction proposes. Under Allergan's constructions, "lightly crosslinked HA" could meet the claim limitation of "uncrosslinked HA" (because it is by agreement "water soluble"), but also meet this definition of "crosslinked HA" (because under Allergan's definition, "crosslinked HA" need not be water insoluble to meet the limitation).

In their opening brief Allergan notes that "the patent distinguishes some HA that is crosslinked from the scope of what the patent considers "crosslinked HA." Allergan concedes that the patents categorize lightly crosslinked HA **as water soluble** and therefore as 'free HA' or 'uncrosslinked HA.'" Pl.'s Br. at 14. Allergan therefore concedes what Valeant said in its opening brief; the definition of lightly crosslinked HA as "water soluble" is necessary to distinguish what, under the patent, is truly "crosslinked HA". That distinction only works if "crosslinked HA" is clearly defined as water-insoluble.

Allergan's approach contradicts the very purpose of the patent's distinction between uncrosslinked HA and crosslinked HA, and Allergan's concession that "lightly crosslinked HA" belongs in the uncrosslinked HA column because it is water insoluble.

Degree of Crosslinking

Allergan, in their attempt to expand their claims to encompass Valeant's products, objects to construing the claimed "crosslinked HA" to require a 2% to 20% degree of crosslinking. But this limitation was explicitly imposed upon the patents by the inventor himself and should be included in any proper construction.

Allergan argues that the patents "[do] not set an absolute ceiling on the associated degree of crosslinking" and "do not specify any degree of crosslinking that the crosslinked HA of the claimed inventions must satisfy." *Id.* at 17. Yet, in both the '475 Patent, at 9:31-33, and the '795 Patent, at 10:22-24, the inventor clearly states that "[t]he degree of crosslinking in the HA component of the **present compositions** is at least about 2% and is up to about 20%." (emphasis added). According to the inventor, the claims of the patents reached only compositions with a

degree of crosslinking between 2% and 20%; any other degree of crosslinking is outside the range covered by the patents and was explicitly disclaimed.

The patentee's use of the term "present compositions" defines the scope of his invention. *See Astrazeneca AB v. Hanmi USA, Inc.*, No. 2013-1490, 2013 U.S. App. LEXIS 25199, *8-9 (Fed. Cir. Dec. 19, 2013) (finding the term "the present invention" to be a disclaimer); *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009) ("Moreover, when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment. . . . Here, the specification frequently describes an 'intraluminal graft' as **'**the present invention' or 'this invention,' indicating an intent to limit the invention to intraluminal devices."); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (importing limits from specification when patent referred to "this invention" or "the present invention"). The patentee's use of the phrase "present compositions" instead of "present invention," when, as in this case, the invention is a composition, it is a distinction without a difference. In short, "[p]atent scope should be coextensive with what the inventor invented as evidenced by what is disclosed in the patent specification." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 815 (Fed. Cir. 2007). And the inventor clearly provided a range of 2-20% within which all of the compositions must fall.

Allergan argues that the existence of disclosed embodiments within this 2-20% range somehow means that the inventor's disclaimer cannot be applied. But quite the opposite is true. The fact that the degree of crosslinking for each disclosed embodiment, in both the '475 and '795 Patent, fall within the 2% to 20% range within which the inventor is quite consistent with the 2-20% limitation.

Allergan also point to claim 27 of the '475 Patent, where a construction of crosslinked HA to include the 2% to 20% range would result in the same claim limitation applied twice in the same claim. Claim differentiation and an aversion to redundancy resulting from the inventor's role as lexicographer does not overrule the canons of claim construction. *See, e.g.*,

Edwards Lifesciences LLC, 582 F.3d at 1329 (affirming construction importing limitation "intraluminal" from specification for term "graft" even though some claims already contained the modifier "intraluminal" when describing grafts); *Nystrom v. Trex Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005) (affirming construction of "board" to require "wood" limitation even though one claim specified a "wood decking board" because of language in written description and prosecution history). Even when courts are faced with a claim construction that would render a claim invalid, not just repetitive, courts do not ignore explicit disclaimers on the scope of the invention to keep that claim alive. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) ("[W]e have limited the maxim [of construing a claim to preserve validity] to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'" (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004)).

As Valeant noted in its opening brief and as discussed above, unless the Court adopts a clear distinction between "uncrosslinked HA" and "crosslinked HA" based on water solubility, lightly crosslinked HA could meet both limitations although Allergan concedes it only belongs in the "uncrosslinked" column. Absent such an approach, the lower bound of 2% provides the separation between the two species of modified HA – crosslinked HA and lightly crosslinked HA.

For the above reasons, the Court should adopt Valeant's proposed construction for the "crosslinked HA" terms.

C. "uncrosslinked HA" / "free HA"

Allergan erroneously claims that the Valeant is ignoring the intrinsic evidence by requiring that the water-soluble HA be added to the crosslinked HA after crosslinking occurs. It is Allergan that is ignoring the intrinsic evidence in an attempt to gain a broad scope of its claims.

Valeant is not arguing that free or partially crosslinked HA could not exist following the crosslinking process. But, faced with the prior art, the patentee sought to overcome that art by limiting his claims to uncrosslinked HA that is added after the crosslinking process. Having made that election to obtain a patent, the patentee and Allergan must now live with his choice.

There is no dispute that the Patent Examiner rejected the patentee's claims as obvious in light of the *Lebreton* patent. Exhibit 15, May 31, 2011 Office Action at p. 11. There is also no dispute the examiner understood *Lebreton* as stating that 6.5% of its composition was crosslinked, and therefore, according to the examiner, the remaining 93.5% should be uncrosslinked. Exhibit 7, Nov. 9, 2011 Response to Office Action at p. 11. To overcome this reference, Allergan distinguished *Lebreton*[2] arguing that the examiner failed to appreciate the significance of adding 6.5% crosslinker and that when understood properly, the *Lebreton* composition would, in fact, contain no free/uncrosslinked HA. *Id.* at 12 In their own words, there would be an "infinitesimally small" chance that any free HA remained after crosslinking. *Id.* at 11-12.

The reason for this "infinitesimally small" chance, according to the patentee, is that, the HA in *Lebreton* had 3,855 potential crosslinking locations on **each** polymer chain. *Id.* at 11. Adding the 6.5% crosslinker would likely supply sufficient crosslinker for each HA polymer to be actually crosslinked at 250 locations on average. *Id.* Given the large number of potential crosslinks and the large number of actual crosslinking cites per polymer chain, the patentee asserted no HA would remain uncrosslinked. Using this same logic, even the 2% lower bound set forth by the Allergan in the '475 and '795 Patents should result in an average of 77[3] crosslinked locations per HA, making it just as unlikely that there would be any free HA.

The foregoing representations to the PTO disavow any composition where the only free HA is what remained after crosslinking. The examiner certainly understood exactly what was being disavowed. After considering the patentee's response that with only 6.5% crosslinking agent added there would be no uncrosslinked HA remaining, the examiner dropped his reliance on *Lebreton* to reject the claims. Instead, he immediately moved to *Reinmuller II* specifically because that patent taught adding uncrossed HA **after** the crosslinking process. Exhibit 8, Jan. 30, 2012 Office Action at 7-8. The applicant then distinguished *Reinmuller II* only on the basis that it did not

[2] Both the prior art *Lebreton* patent and the patents-in-suit have the same inventor.
[3] This result is reached by multiplying 250 by the ratio of 2% to 6.5%.

teach the addition of free/uncrosslinked HA in the correct concentrations. Exhibit 9, July 30, 2012 Office Action at p. 11.

To paper over the prosecution history of the '475 Patent, Allergan now argues that Valeant is "attempt[ing] to improperly convert these claims into product-by-process claims." Pl.'s Br. at 21. But that is not what Valeant is doing. Valeant's construction merely provides an instruction on how to determine what is "uncrosslinked HA" and what is not "uncrosslinked HA" for purposes of the patent.

And even if Valeant's construction requires a specific process, incorporating a process into a product claim is not improper when that limitation is required. *See, e.g., TechRadium, Inc. v. Edulink Sys. Inc.*, No. H-10-1887, 2012 U.S. Dist. LEXIS 189753, *17 (S.D. Tex. July 16, 2012) ("When the patent prosecution history includes a statement from the inventor that a process is necessary to obtain a product, the inventor disclaims methods of producing that product that do not involve that step"). The patentee, in order to keep their claims alive, represented to the Patent Examiner that the prior art did not render their claims obvious because neither had (a) taught the *adding* of free/uncrosslinked HA following the crosslinking process (b) in the proper proportions. Without these disclaimers, both *Lebreton* and *Reinmuller II* would have rendered the claims at issue invalid.

Allergan additionally argue that Valeant's construction must not be correct because a dependent claim would be rendered superfluous. But claim differentiation is merely a presumption, which "can be overcome by a contrary construction required by the specification or prosecution history, such as via a disclaimer." *GE Lighting Solutions, LLC v. Agilight, Inc.*, No. 2013-1267, 2014 U.S. App. LEXIS 8202, at *9 (Fed. Cir. May 1, 2014); *see also Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1097 (Fed. Cir. 2013) ("Our cases make clear . . . that where found, prosecution history disclaimer can overcome the presumption of claim differentiation.") The patentee was faced with losing his claims during prosecution due to the *Lebreton* and *Reinmuller II* prior art. To avoid this, the patentee made the deliberate decision to limit his claims to compositions

where the free/uncrosslinked HA was added after crosslinking occurred and in an amount that exceeded what was taught in *Reinmuller II*. It is not the "Defendants' construction [that] would change the very nature" of the claims (Pl.'s Br. at 22); it is the patentee's disclaimer.

The patent examiner issued these patents based upon the modified understanding of free/uncrosslinked HA established through prosecution. As Allergan noted in their opening claim construction brief, statements during prosecution of an application "'limit[] the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'" *Springs Windows Fashions LP v. Novo Indus., Inc.*, 323 F.3d 989, 994 (Fed. Cir. 2003) (citation omitted). Without this restriction, patentees could "recaptur[e] through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-24 (Fed. Cir. 2003). This is precisely what Allegan is attempting to do here.[4]

For these reasons, Valeant urges the Court to adopt their construction.

III. CONCLUSION

This Court should adopt Valeant's proposed constructions.

Dated: June 27, 2014

/s/ William F. Cavanaugh, Jr.
William F. Cavanaugh, Jr.
PATTERSON BELKNAP WEBB & TYLER LLP
Attorneys for Defendants

[4] Allergan also argues that the claim construction proposed by Valeant should not be adopted because Valeant does not add uncrosslinked HA. That is no reason to ignore the patentee's disclaimer. Allergan should not be permitted to expand the scope of their claims to encompass what they could not claim earlier because of *Lebreton* and *Reinmuller II*.